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| 09/626,636 | 07/27/2000 | Gary Karlin Michelson M D | 102.0003-04000 | 6124 |
| 22882 | 7590 | 05/17/2006 | EXAMINER | |
| MARTIN & FERRARO, LLP 1557 LAKE O'PINES STREET, NE HARTVILLE, OH 44632 | | | HO, UYEN T | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3731 | |
| DATE MAILED: 05/17/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/626,636

Applicant(s)

MICHELSON M D, GARY KARLIN

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 172-276 and 278-343 is/are pending in the application.
- 4a) Of the above claim(s) 185-189, 196-200, 203-206, 227-236 and 239-246 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 207-226, 237, 238 and 289-330 is/are allowed.
- 6) ☒ Claim(s) 172-184, 201, 202, 247-269, 276, 278-288 and 331-343 is/are rejected.
- 7) ☒ Claim(s) 190-195 and 270-275 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/23/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 172-175, 177, 219, 257 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to define or disclose the guard being contoured to the curvature of the adjacent vertebral bodies. The specification

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 172-175, 177, 219, 257 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "contoured to the curvature of the adjacent vertebral bodies" in claim 172 is a relative term which renders

the claim indefinite. The term "contoured to the curvature of the adjacent vertebral bodies" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The adjacent vertebral bodies are varying in shape in reality depending on different patient and different vertebrae. It is unclear that "being contoured to the curvature to the curvature of the adjacent vertebral bodies" is as being custom made to fit to the curvature of the adjacent vertebral bodies or the guard being configured to every curvature of the adjacent vertebral bodies or every patient or is a particular shape that applicant wish to claim. Examiner is also unclear about the boulder of "the curvature of the adjacent vertebral bodies." Therefore, the distal end of the guard as claimed cannot be defined.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 172-178, 181-184, 247, 331 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (5,015,255) in view of Cozard (5,049,150). Kuslich discloses a guard (104), a distractor (fig. 5), Kuslich discloses all the limitation except for a presence of engaging portions and flat portions between the engaging portions. Cozard disclose guard for bone surgery and including engaging portions and flat portions as

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claimed (fig. 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the engaging portion and flat portions in view of Cozad into Kuslich's guard sleeve (104) in order to provide an engage mechanism that prevent the guard from moving so that the insertion could be more accurate.

8. Claims 172-184, 201, 202, 247-269, 276, 278-288, 331-343 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ma et al. (3,848,601) further in view of a well known in the art. Ma et al. disclose all the limitations of the claims except for a presence of a flat portion between spine engaging portions. Although, Ma et al. disclose the depth limit configuration does not including a flat portion between the engaging portions or penetrating portions, it is known in the art to have depth limit configuration including a flat portion between the engaging portions of penetrating portions (see Staubli 5,058,275). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a flat portion between penetration portions of the chisel of Ma et al.'s device for limit the depth penetration of the chisel. Doing so would amount to mere substitution of one configuration for another configuration within the art that would perform equally well in the Ma et al.'s device.

9. Claims 172-184, 201, 202, 247-269, 276, 278-288, 331-343 are rejected under 35 U.S.C. 103(a) as being unpatentable over Codman (Signature Series 4) in view of Cozad (5,049,150). Codman disclose all the limitations of the claims except for a presence of the engaging portions do not substantially increase the outer cross

sectional dimension of the guard near the distal end of the guard. It is well known in the art to have a guide sleeve having penetrating members and a flat portion formed integrally with the sleeve for example, Cozad reference discloses engaging portion do not substantially increase the outer cross sectional dimension of the guard and formed integrally with the sleeve. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Codman reference by having the a guide sleeve having penetrating members and a flat portion formed integrally with the sleeve to reduce the step of making and material for forming a guide sleeve.

Allowable Subject Matter

10. Claims 207-226, 237, 238, 289-330 are allowed. Claims 190-195, 270-275 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is 571-272-4696. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN NGUYEN can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Jackie Tan-Uyen T. Ho', with a long horizontal flourish extending to the left.

(Jackie) Tan-Uyen T. Ho
Primary Examiner
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May 9, 2006